

REMARKS

Claims 6 and 9-10 are all the claims pending in the application.

Claims 6 and 10 are amended for further clarity.

Claim 6 is also amended to recite that the additional yeast extract added is in an amount of 0.05 to 0.2 % per liter of the raw milk. Support for the amendment to claim 6 can be found in the specification, for example, at page 14, first paragraph, where it describes that “[T]he yeast extract is preferably added in an amount of from 0.05 to 0.2% per liter of a milk component”. In this connection, the specification discloses on page 10, lines 5-6 from the bottom, that milk component before formation of a curd may be raw milk. Therefore, the amendment in claim 6 is supported by the specification.

No new matter has been introduced. Entry of the Amendment is respectfully requested.

I. Response to Claim Rejection under 35 U.S.C. § 112, first paragraph

Claims 6 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

(1) The Examiner asserts that the instant specification does not provide written description for the recitation of claim 6 that “the incubation of a lactic acid bacteria starter in culture medium.” In this regard, the Examiner asserts that Example 3 of the present application relates to only *L. gasseri* and *Lactococcus lactis* not to *any lactic acid bacteria* as presently claimed.

Applicants respectfully traverse.

The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” See MPEP 2163.02.

In the present case, the specification reasonably conveys to the artisan that the inventor had possession that the instantly claimed process for producing a natural cheese includes a step of **incubating a lactic acid bacteria starter** comprising a lactic acid bacteria with culture medium containing milk to which yeast extract is added. In this regard, the instant specification at least provides the following disclosures.

Example 3 of the present application is directed to a process for producing *L. gasseri*-enriched gouda cheese. The Examiner is correct that Example 3 uses *L. gasseri* starter and *Lactococcus lactis* starter. However, the entire disclosure of the specification should be considered when determine if the specification reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.

The specification describes, at page 10, that in the production of the natural cheese of the present invention, *L. gasseri* is preferably added as a *L. gasseri* starter, and the *L. gasseri* starter can be used together with a lactic acid bacteria starter for cheese. Also, the specification describes, at pages 11-12, that each of the *L. gasseri* starter and a lactic acid bacteria starter which are prepared in a method described in Example of the present invention are preferably added to the raw milk from 0.5 to 5%, more preferably 1%, per kg of the raw milk, to take each of *L. gasseri* viable cells and lactic acid bacteria viable cells at a final amount of about 10^6 to 10^7 cfu.

Claim 6 has been amended for further clarify to recite a process for producing a natural cheese, which comprises (1) incubating a lactic acid bacteria starter with a culture medium containing milk to which yeast extract is added, wherein the lactic acid bacteria starter comprises a lactic acid bacterium belonging to *Lactobacillus gasseri* having a disinfection potency against *Helicobacter pylori*.

(2) Regarding the recitation “adding additional yeast extract to the raw milk” of claim 6, the Examiner asserts while in Example 3, additional yeast extract is added to the milk (for cheese making), the broad claim of “adding additional yeast extract to the raw milk” is not supported by the specification as originally filed. According to the Examiner, the specification as originally filed supports the addition of yeast extract but not the number of times it can be added. See Office Action, at page 3, first paragraph.

Applicants respectfully traverse.

The specification of the instant application, in particular Example 3, clearly describes that in the process of making cheese, the yeast exact are added twice. It is respectfully submitted that any person skilled in the art to which the invention pertains reading the instant specification and Example 3 would readily understand that the inventor had possession at that time of the invention of the claimed subject matter, of a conception and reduction to practice that the yeast exact are added twice during the cheese manufacturing process.

In view of the above, withdrawal of the foregoing rejection of claims 6 and 9-10 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

II. Response to Claim Rejection under 35 U.S.C. § 112, second paragraph

Claims 6 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

(1) The Examiner asserts that claim 6 is indefinite for the recitation “incubating a lactic acid bacteria starter comprising a lactic acid bacteria with culture medium containing milk component where in yeast extract is added”. According to the Examiner, it is not clear what the “milk component” is.

Without acquiescing in the merits of the rejection, claim 6 has been amended to recite “culture medium containing milk”. This amendment is supported at least by Example 3 of the present application.

(2) The Examiner asserts that claim 6 is indefinite for “a lactic acid bacteria starter comprising a lactic acid bacteria,” on the grounds that since a lactic acid bacteria starter contains lactic acid bacteria, it is not clear what is meant by lactic acid bacteria comprising lactic acid bacteria.

Applicants respectfully traverse.

Present claim 6 recites incubating a lactic acid bacteria starter with a culture medium containing milk to which yeast extract is added. It is respectfully submitted that present claim 6 satisfies the requirement under 35 U.S.C. 112.

(3) Claim 10 is allegedly being indefinite for the recitation of “a mutant thereof”. The Examiner contends that it is not clear whether the mutant has the same properties as the parent species regarding the disinfecting ability against *H. pylori*.

Without acquiescing in the merits of the rejection, claim 10 has been amended to delete the recitation “a mutant thereof.”

In view of the above, withdrawal of the foregoing rejection of claims 6 and 9-10 under 35 U.S.C. §112, second paragraph, is respectfully requested.

III. Claim Rejections under 35 U.S.C. § 103

Claims 6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner et al. (1998, Development of a probiotic cheddar cheese containing human-derived *Lactobacillus paracasei* strains; hereinafter R1) in view of Anderson et al. (US 3,852,158;

hereinafter R2), Germond et al. (WO 0188150, hereinafter R3) and Kimura et al. (EP 1 112 692 A1, hereinafter R4).

Applicants respectfully traverse.

(1) The above rejection should be withdrawn because Gardiner in view of R2, Kimura and/or Germond, does not disclose or render obvious the claimed process for producing a natural cheese, as recited in present claim 6, where yeast exact is added twice during the process.

As noted, the process for producing a natural cheese of present claim 6 requires that the yeast exact are added twice during the claimed process.

In this regard, as described in Example 3 of the present application, *L. gasseri* OLL 2716 was inoculated at a ratio of 1% into a 10% skim milk medium containing 0.1% **yeast extract**. Then *L. gasseri* was cultured at 37°C for 24 hours, thereby giving bulk starters. Subsequently, 20 kg of partially skim milk (SNF 8.5%, fat 3%), which had been sterilized at 73°C for 15 seconds, was adjusted to 32°C and inoculated with 1% of the *L. gasseri* bulk starter. Next, 20 g of **yeast extract** was further added. Then cheese curd was produced by a conventional method, pressed and **incubated** in a mold in a room at a room temperature of 25°C for 24 hours.

Example 3 is an example to the effect that, in a process of making cheese, first adding an yeast extract to a 10% skim milk to make bulk starter containing *L. gasseri*, **and** then adding additional yeast extract after adding the lactic acid bacteria bulk starter to raw milk and before formation of the curd in step (2). That is, in the process for producing a natural cheese according to the present invention, the yeast exact are added twice during the process.

It is respectfully submitted that the cited references, alone or in combination, do not disclose or teach a process for producing a natural cheese where the yeast exact are added to the

process twice, as required by independent claim 6 of the present application. For this reason, the present claims are patentable over Gardiner, in view of R2, Kimura and/or Germond.

(2) In the present Action, the Examiner cites R2 (Anderson) as allegedly disclosing the utilization of yeast extract in the activation and propagation of starter cultures normally used in cheese making.

In particular, the Examiner asserts that since R2 (Anderson) discloses the utilization of yeast extract in the activation and propagation of starter cultures normally used in cheese making, *addition of the yeast extract at any stage in the cheese making before the formation of curd would be obvious*. See Office Action, at page 8, second paragraph. The Examiner further asserts that R2 discloses the utilization of yeast extract in the activation of the propagation of starter cultures, R3 teaches incorporating *L. gasseri* in cheese as a suitable delivery system. The Examiner then concludes that when the yeast extract is included in the cheese together with *L. gasseri*, the result of high viability of *L. gasseri* would be reasonably expected.

Applicants respectfully disagree.

It is respectfully submitted that the instantly claimed timing and the times (i.e., yeast exact are added twice) of addition of yeast extract to the process are critical and provide unexpected superior results. Contrary to the examiner's assertion, it is not the same (or obvious) to just add the yeast extract at any stage in the cheese making before the formation of curd.

(3) Further, the process for producing a natural cheese according to the present invention provides unexpectedly superior property,

In this regard, Applicants provide herewith a first executed Rule 132 Declaration ("Declaration 1") by Mr. Mitsuro Matsuo that the natural cheese according to the present invention exhibits unexpectedly superior result, and such unexpectedly superior result is at least

demonstrated by Fig. 3 of the present application. Fig. 3 of the above-identified application shows bacterial count changes in *L. gasseri*-enriched gouda cheese according to Example 3 of the above-identified application, over the time period of six months.

In Example 3, *L. gasseri* OLL 2716 was inoculated at a ratio of 1% into a 10% skim milk medium containing 0.1% yeast extract. Then *L. gasseri* was cultured at 37°C for 24 hours, thereby giving bulk starters. Subsequently, 20 kg of partially skim milk (SNF 8.5%, fat 3%), which had been sterilized at 73°C for 15 seconds, was adjusted to 32°C and inoculated with 1% of the *L. gasseri* bulk starter. Next, 20 g of yeast extract was further added. Then cheese curd was produced by a conventional method, pressed and incubated in a mold in a room at a room temperature of 25°C for 24 hours.

As shown in Fig. 3 of the present specification, when yeast extract was added in the process of making curd and incubation the curd was carried out in order to increase bacterial count of lactic acid after preservation, high bacterial count can be kept for a long period of time (e.g., six months or longer) during preservation in case of using *L. gasseri* OLL2716 while bacterial count was dramatically decreased in case of using bacteria other than *L. gasseri* OLL2716. Fig. 3 shows unexpected results of the present invention and shows that the constant high bacterial counts over the six month period of time was obtained only when employing the conditions recited in the claims.

Specifically, in case where cheese containing lactic acid bacteria is produced according to conventional method, cheese containing specific amount of lactic acid bacterium may be obtained. However, bacterial count in the cheese is decreased during preservation (for example, see Fig. 2 of the present specification).

Therefore, maintaining high bacterial count even after preservation of cheese is desired.

To achieve the object of increasing bacterial count in cheese after preservation, additional yeast extract was added in the process of making curd and incubation step of the curd was carried out. However, it was revealed that bacterial count of lactic acid was dramatically decreased.

After intensive investigation by the inventors of the present application, the inventors of the present application found the unexpected effect that when both steps of a) addition of yeast extract in production of the curd and b) incubation step after production of the curd were carried out, high bacterial count in preservation of cheese was kept in case of using *L. gasseri* OLL2716.

The process for producing a natural cheese according to the present invention requires the selection and the combination of the following three particular features: i) election of *L. gasseri* OLL2716; ii) addition of yeast extract in production of the curd; and iii) incubation step after production of the curd in specific condition. The combination of these three features was not disclosed, taught or suggested in the cited references.

Because the presently claimed process for producing a natural cheese provides unexpected results in that bacterial count of lactic acid during preservation of cheese can be kept high was obtained, such unexpected properties are evidence of the non-obviousness of the claimed invention.

(4) Addition of Yeast Extract

In general, yeast extract is not added during production of cheese since it has a bad influence in flavor. Additionally, since cost of yeast extract is relatively high, it is usual that low amount of yeast extract is used. Therefore, in case of normal cheese for which increase in survival rate of lactic acid bacteria in cheese is not necessary, yeast extract is not added.

(5) Amount of Yeast Extract

Also, the above rejection should be withdrawn because Gardiner in view of R2, Kimura and/or Germond, does not disclose or teach the presently claimed process for producing a natural cheese wherein the yeast extract added is in amount of 0.05 to 0.2 %.

Claim 6, as amended, recites that the yeast extract added is in an amount of 0.05 to 0.2 % per liter of milk.

In the present Action, R2 (Anderson) is cited by the Examiner as allegedly disclosing the utilization of yeast extract in the activation and propagation of starter cultures normally used in cheese making.

However, R2 does not disclose or teach the instantly claimed amount of yeast extract. In this regard, to facilitate the Examiner's review, Applicants provide herewith a second executed Rule 132 Declaration ("Declaration 2") to show the calculated amount of yeast extract that is added to milk for cheese according to R2. Based on the evidence demonstrated in executed Rule 132 Declaration 2, it is clear that the amount of yeast extract used in the process of R2 is much lower than that of the present invention.

In the process for producing a natural cheese according to the present invention, larger amount of yeast extract is added as compare to that of R2. For example, in Example 3 of the present application, the amount of the yeast extract which is carried from medium culture to the starter is:

$$0.1\% \text{ (combination ratio of yeast extract in medium)} \times 1\% \text{ (amount added to milk for cheese)} = 0.001\%$$

And, in Example 3, the direct addition of milk (additional yeast extract)

$$20 \text{ g (yeast extract)} / 20 \text{ kg (milk)} = 0.1\%$$

Thus, in Example 3 of the present application, the total amount of yeast extract added to milk is 0.101% (i.e., 0.001% + 0.1%) per liter of milk.

The amount of yeast extract added as in Example 3 in the present application is larger than the amount of yeast extract added according to R2 as calculated and demonstrated in the executed Rule 132 Declaration.

Conclusion

In summary, the cited references, either alone or in combination does not disclose or render obvious the claimed process for producing a natural cheese, as recited in present claim 6, where yeast exact are added to the process twice, and where the yeast extract added is in amount of 0.05 to 0.2 %. Further, because the presently claimed process for producing a natural cheese provides unexpected results in that bacterial count of lactic acid during preservation of cheese can be kept high was obtained, such unexpected properties are evidence of the non-obviousness of the claimed invention.

In view of the above, Applicants respectfully submit that the present claims are patentable over Gardiner, in view of R2, Kimura and/or Germond. Reconsideration and withdrawal of the present § 103(a) rejections of claims 6 and 9-10 are respectfully requested.

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111
Application No.: 10/510,497

Attorney Docket No.: Q84102

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